

Nanotech Commercialization Has Advanced, but Government Action to Address Risk Has Not

Testimony before the House Committee on Science

Matthew M. Nordan, President, Lux Research Inc., September 21, 2006

Global sales of products incorporating nanotechnology are more than doubling annually, but environmental, health, and safety (EHS) risks threaten to stall commercialization. Industry sees three key concerns: Real risks, perceptual risks, and regulatory risks. Awareness among the scientific community is already in place and multiple, well-developed lists of research needs are already built. Now, the federal government must establish a game plan for basic research – which will require a new interagency body with the authority to implement that plan – and supply adequate funding to carry it out. These actions will enable companies to carry out their own research on specific applications, and help address perceptual and regulatory risks in the bargain.

Nanotech EHS Issues Still Confront Industry

Since the House Committee on Science last held hearings about the environmental, health, and safety (EHS) risks of nanotechnology in November 2005, the debate about whether and how nanoparticles might injure workers, harm consumers, or damage the environment has intensified.¹ Nanotech's growing commercial success – \$32 billion in products incorporating nanotech were sold in 2005 – has meant increased scrutiny of EHS issues from advocacy groups and regulators, and increased urgency among companies developing products that incorporate nanoparticles (see Figure 1).² Lux Research studies the commercialization of nanotechnology and advises companies about how they should approach nanotech opportunities, and when it comes to EHS issues, we see three key concerns faced by industry (see Figure 2):³

- **Real risks of nanoparticles.** Companies working with nanoparticles – like metal nanopowders, carbon nanotubes, and quantum dots – need to ensure that their materials and applications won't harm people or the environment. But considerable uncertainty surrounds real risk because the hazards

Lead Author

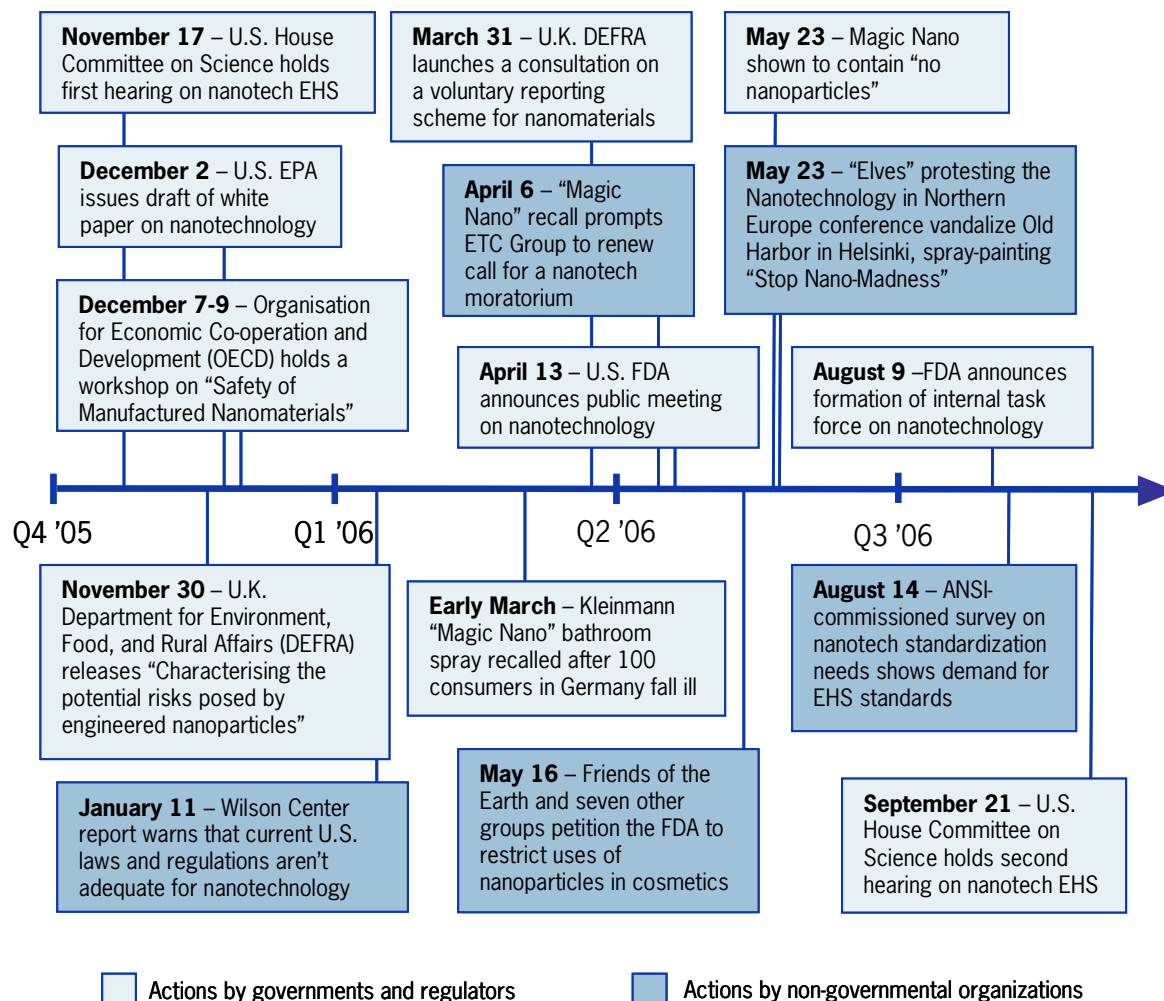
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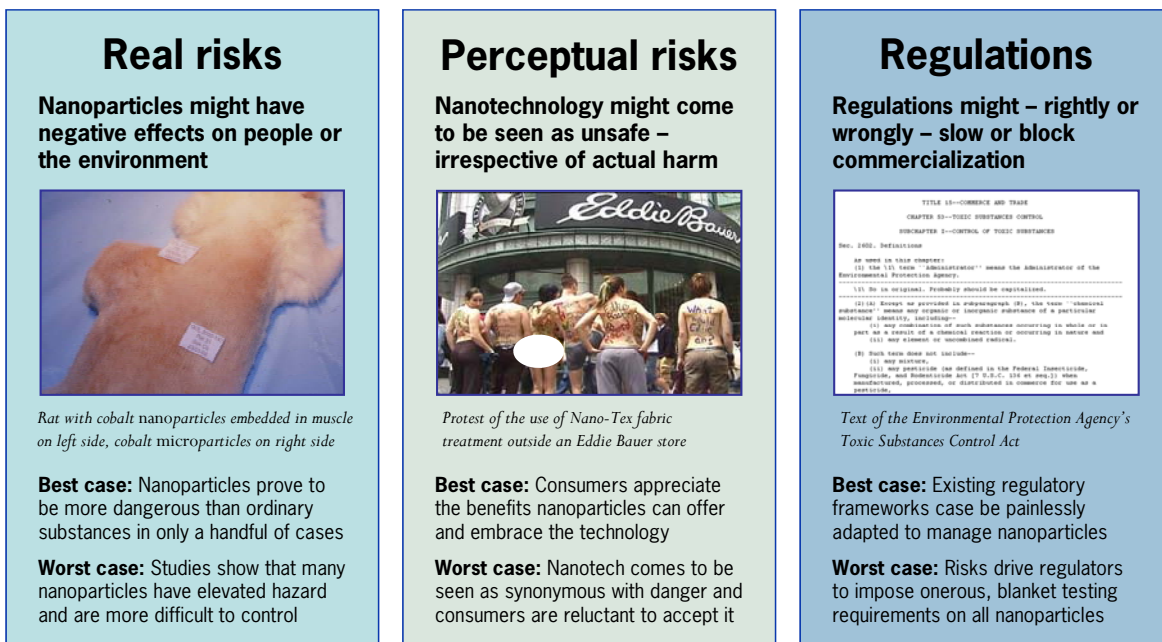
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Fig. 1: Notable Nanotech EHS Events since the House Science Committee's First Hearing

of most nanoparticles are not well understood, exposure can be difficult to predict and measure, and even solid scientific studies arrive at contradictory results. For example, researchers at Rice University's Center for Biological and Environmental Nanotechnology found that even at low concentrations, fullerenes are toxic to bacteria and human cells in water; however, others at the Université Paris XI found the same particles not only safe but beneficial, protecting lab rats' livers from damage caused by other chemicals.⁴ While scientists debate, companies like General Electric must forge ahead *now* with decisions about how to invest in nanotech R&D, partnerships, and products.

- **Perceptual risks when real dangers are unknown or misunderstood.** Regardless of the real risks presented by any given nanoparticle or application, firms developing products using nanoparticles could find commercial feasibility blocked by the *perception* that the materials are

Fig. 2: Industry's Nanotechnology EHS Concerns Fall into Three Categories

dangerous – even if they are proven safe. Public perception of nanotechnology in the U.S. remains largely undetermined to date, with public opinion surveys continuing to show low awareness of nanotechnology and high optimism. A 2005 U.S. study found that just 16% of respondents rated themselves “at least somewhat informed” about nanotech, but in the same study 66% agreed with positive statements about the field.⁵

However, many non-governmental organizations opposed to nanotech development – particularly those overseas – have grown more forceful in their protests. In May 2006, the environmental group Friends of the Earth issued a fiery report on the use of nanoparticles in cosmetics and sunscreens, condemning companies for “treating their customers like guinea pigs” and calling for a ban on the use of nanomaterials in these products. When the French government’s Minattec nanotechnology research center opened in May 2006, protestors stormed conference rooms and accosted scientists on the street. Such reactions make firms like Johnson & Johnson look at the decades-long public relations and legal battles over supposedly dangerous products, from silicone breast implants to red M&Ms, and wonder whether even the safest nanoparticles could become a liability.

- **Regulations – or lack thereof.** U.S. companies will also have to abide by regulations of nano-enabled products and processes, ranging from workplace guidelines under the Occupational Health and Safety Administration to restrictions on the release of materials by the Environmental Protection Agency (EPA) – as well as regulations in the other countries where they do business.

The EPA held a public meeting in June 2005 to solicit comments on a proposed voluntary pilot program that would collect data on nanomaterials. In December it issued a regulatory decision on carbon nanotubes, the first nanoparticle submitted to it under the Toxic Substances Control Act, approving the material for manufacturing under a low release and exposure exemption; the EPA also issued a broad draft white paper on nanotechnology in the same month. Meanwhile, the Food and Drug Administration (FDA), National Institute for Occupational Safety and Health, and Consumer Product Safety Commission have all issued position papers on nanotechnology. The FDA has also gone further, announcing the formation of an internal task force and calling public meetings on nanotech.

Despite all the action, regulatory ambiguity persists – it's still often not clear how current regulations apply to nanoparticles or whether and when agencies will issue new ones – leaving firms that work with nanoparticles confused about how to plan for regulatory rulings. While companies are generally pleased about how the EPA, for example, has communicated with them so far, they're also frustrated by how slow those agencies have been to set specific guidance, like the EPA's long-proposed voluntary Stewardship Program for nanoparticles.

With nanotech continuing to shift more and more from “R” to “D” and into products – \$150 billion worth of nano-enabled products will be sold by 2008 – sound policy to help firms manage these risks effectively is more urgent than ever.

EHS Risks Are a Gating Factor for U.S. Nanotechnology Leadership

Our firm conducts hundreds of interviews, site visits, and advisory sessions each year with executives and scientists responsible for nanotech at large corporations, as well as leaders of start-ups specializing in nanotech. Our conversations with them rarely fail to touch on EHS issues. We hear that even as many U.S. corporations and start-ups drive nanotech commercialization forward, others are cancelling their efforts or failing to find funding and support for them due to EHS risks.

- **The sheer cost of real risk dissuades companies from worthy endeavors.** Without the data, tools, and frameworks needed to manage the real risks of nanoparticles, large corporations retrench rather than expose themselves to undue liability or sink millions into toxicity tests. Meanwhile, nanotech start-ups face an even tougher situation – they have little hope of funding such research on their own, yet their customers expect them, like any other supplier, to come equipped with data on health effects. Interviewees consistently cite nanoparticle EHS concerns as a major topic of discussion, and even a bargaining chip, in partnership negotiations.

“We’ve stopped development where costs were too high to ensure no exposure or risk across the life cycle, or where we couldn’t clearly judge hazard potential due to the lack of accepted methods. It’s quite complicated; we can’t set decision points today.” (Corporation)

“The BASFs, Degussas, and DuPonts of the world come in with their act together, but start-ups typically say, ‘Oh, we didn’t bring the EHS guy with us.’ We’ve canceled several projects because of a lack of EHS information from the supplier. We could generate the information ourselves, but it’s just not worth it.” (Corporation)

- **Perceptual risks threaten to drive “nano” underground.** Companies are universally concerned about perceptual risks but don’t know how to handle them, and many try to duck the issue by simply forbidding the term “nanotechnology” – a dangerous strategy that risks a backlash. Executives at Estée Lauder reportedly held a special meeting in early 2006 to instruct employees, brand managers, and customer relations people to cease any use of or reference to the term. Solar-cell maker Konarka takes pains never to mention the fullerenes it uses in its flexible photovoltaics, lest EHS fears about fullerenes damage the “clean and green” message it emphasizes to investors and the public. Even companies that are comfortable with the real risks of their materials don’t trust their buyers to make informed decisions about them:

“We promote the benefits better products bring without talking about technology. With nanotech, it’s no different: You won’t hear us talking about nanotech or advertising it in any way. That’s our strategy for dealing with potential negative publicity.” (Corporation)

“Our strategy is pretty clear. Focus on features and benefits; give the products names associated with benefit of product; don’t put ‘nano’ in the name of the product.” (Start-up)

- **Corporations are eager for regulation; among start-ups, paranoia reigns.** Contrary to what one might expect, large corporations consistently *want* to see clear regulatory guidance on nanoparticles, which they feel will ensure a level playing field and tell them what to plan for. These firms are enthusiastic about the EPA’s approach – which lets them participate in its deliberations and gain insight into its thought processes – but frustrated by agencies like the FDA that have communicated less on key issues. With start-ups, on the other hand, we frequently hear the plea for “rational” and “science-based” regulations – subtext for fears that regulators will overreach and impose sweeping and onerous rules that could kill their businesses.

“Our CEO decided it was too early to make any more investments in nanotech until the FDA makes some decisions on how it will be handled. We’re all very disappointed about this, since we have already dedicated significant resources.” (Corporation)

“For some of our product categories, a full battery of tests might cost \$40 million. But if it’s a reformulation of an existing compound, it could be only a few hundred thousand. Right now with nano we have no idea which it will be.” (Corporation)

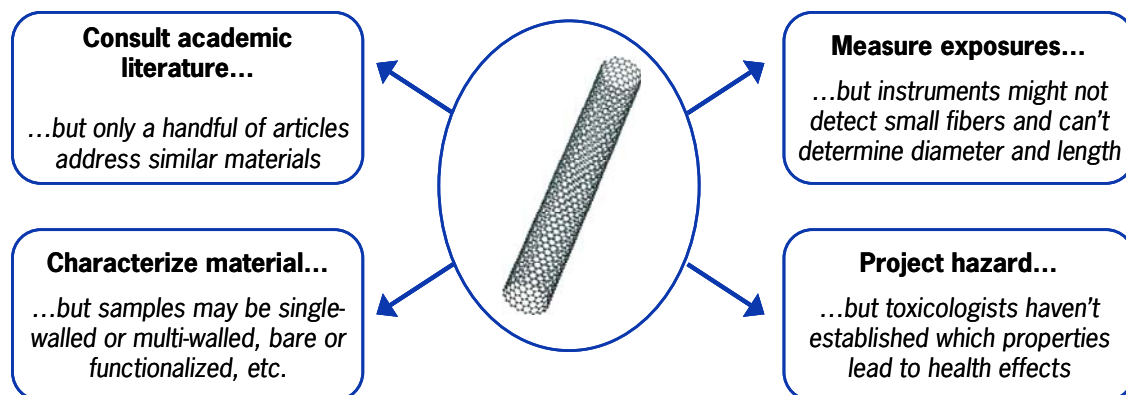
“We’re working very hard to make sure regulations are in place. Everyone benefits from strong, robust regulations – not only to protect consumers, but to level the playing field for companies, so that everyone puts the right amount of thought into protecting health and assessing safety.” (Corporation)

“I’m concerned about the regulatory environment. We need (real risk data), or we’ll get regulated to levels that don’t make sense in terms of facts. Our concern is that regulations will change not based on fact, but based on hysteria... hopefully the regulators won’t do something silly.” (Start-up)

“I have no idea how (regulation) is going to evolve. It could be very factual and science-based, or it could be very politicized. We’d like to influence it and have it be rational.” (Start-up)

The combination of the struggles firms face around all three factors is leading to adverse consequences for industry and the U.S. economy, as promising innovations get de-prioritized in corporate R&D budgets for reasons unrelated to performance, price, and market demand. The results can be particularly dire for the small firms that our technologically-driven economy relies on to develop crucial innovations. Venture capitalists are beginning to shrink from funding start-

Fig. 3: Lack of Specific Data Makes it Difficult to Apply Risk Management Techniques to Nanotech



ups that face nanotech EHS risks, as prominent U.S. nanotech investor Steve Jurvetson stated in a recent *Nature* article.⁶ Start-ups even struggle to obtain business services: At least one U.S. insurer has cancelled coverage of small companies once it learned they were involved with nanotech.

Government Support for Basic Research Will Help Address Real Risks

Clearly the first and most important responsibility of any company developing nanoparticle applications is to ensure that they won't present hazard to workers, consumers, or the environment. As we have described previously, conventional risk management paradigms – identifying hazard, characterizing hazard, assessing exposure, and characterizing risk – can be applied to nanoparticles, and only applications where both hazard and exposure are present constitute serious risks.⁷ However, many aspects of nanoparticles make them uniquely challenging to address (see Figure 3). These challenges boil down to two key categories of research needs:

- 1) **Lack of specific data.** Simply put, the health and environmental effects of nanoparticles haven't been studied well enough for EHS professionals to assess them confidently. While a vast literature on conventional materials exists for these researchers to draw on, the literature on nanoparticles still lags behind by a wide margin. A scientist working with an organic chemical can very likely turn to the literature and find several papers addressing the health effects the compound she is studying, or at least very similar ones; scientists working with nanoparticles have no such luxury. Of 81,334 peer-reviewed journal articles on toxicology from January 2000 through May 2006, just 0.6% make any mention of nanoparticles – compared with 12% for polymers, a much better-known class of materials.⁸ More specifically, we identified just 316 articles specifically focused on the EHS risks of engineered nanoparticles (through May 2006) from a review of over 1,500 documents drawn from databases of published research like that maintained by the International Council on Nanotechnology (ICON) at Rice University, literature searches using Science Citation Index; and review articles like the report from the International Life Sciences Institute Nanomaterial Toxicity Screening Working Group.⁹

- 2) Lack of well-developed frameworks for understanding real risks.** For more familiar classes of chemicals and materials, long experience has given scientists a good understanding of what characteristics make a substance harmful, so they can make reasonable judgments even when they lack specific toxicity data. In the case of nanoparticles, however, these frameworks (often referred to as “structure-activity relationships”) are only beginning to be developed, and current results often contradict each other. For instance, while Günter Oberdörster at Rochester University found that smaller particles of titanium dioxide (TiO₂) are more harmful than large ones, David Warheit at DuPont found no relationship between size and toxicity; he also found that nanoparticles of silica (SiO₂) and zinc oxide (ZnO) are *less* harmful than larger ones.¹⁰

Nanotech’s critics rightly point out that companies themselves must take responsibility for generating data on the specific materials they work with and applications they put the materials to, and shouldn’t depend on the government to do it for them. This important point addresses the first category of research need above.¹¹ However, the key role for government lies in the second category of research need: Supporting the basic research needed to develop *frameworks* that companies and researchers can put to use in evaluating their own materials. Just as wise government funding produced the fundamental scientific breakthroughs that lead to the *successful* nanotech commercialization we’re seeing today, similar investment in understanding the basic science of nanoparticle EHS factors will underlie *safe* nanotech developments.

Research Priorities Are Well-Understood; What’s Needed Is a Game Plan and Money

In terms of specific research needs, we do not see identification of priority areas of research as being the key roadblock to progress. Multiple well-developed needs lists have already been produced by organizations ranging from the EPA to the Wilson Center, and they all prioritize the development of test methods, hazard screening, and exposure route investigation (see Figure 4). What is missing is not this “ingredients list,” but two things: A specific game plan for accomplishing the research and adequate funding to execute it.

- **A new interagency body must form a nanotech EHS game plan – with authority to execute.** The biggest issue is the absence of a game plan; nanotechnology EHS research in government agencies, academic institutions, and industrial facilities is expanding, but it is being performed in an ad hoc fashion according to individual priorities that both risk costly duplication of effort and raise the specter of key issues remaining unaddressed. The National Science and Technology Council’s Nanotechnology Environmental and Health Implications working group (NEHI), the body nominally in charge of nanotech EHS issues as part of the National Nanotechnology Initiative (NNI), has not yet established a research *strategy* – one that makes the tough decisions about prioritizing specific research tasks, apportioning them to public and private sector entities, and measuring progress. This is not surprising, because NEHI has no authority to mandate such priorities and cannot allocate funding. A new, interagency body with such authority is required to break the deadlock. The effort to establish such an authority and formalize a clear, short-term research plan could be led by NEHI, but also the National Academies’ Board on Environmental Studies and Toxicology or the National Institute of Environmental Health Sciences.
- **Funding must grow.** We continue to believe that the appropriate funding level for addressing nanotech EHS research needs is likely between \$100 and \$200 million annually, or two to four

Fig. 4: More than Half a Dozen Well-Developed Lists of Nanotech EHS Research Needs Exist Now

Group	Date	Document	Available at:
European Commission (EC)	June 2005	Nanosciences and nanotechnologies: An action plan for Europe 2005-2009	cordis.europa.eu/nanotechnology/actionplan.htm
U.S. National Institute for Occupational Safety and Health (NIOSH)	September 2005	Strategic Plan for NIOSH Nanotechnology Research	www.cdc.gov/niosh/topics/nanotech/strat_plan.html
Consortium of researchers	October 2005	Principles for Characterizing the Potential Human Health Effects from Exposure to Nanomaterials: Elements of a Screening Strategy	http://www.particleandfibretoxicology.com/content/2/1/8
U.S. Environmental Protection Agency (EPA)	December 2005	External review draft of nanotechnology white paper	www.epa.gov/osa/nanotech.htm
U.K. Department for Environment, Food and Rural Affairs (DEFRA)	December 2005	Characterizing the risks posed by engineered nanoparticles: A first UK Government research report	www.defra.gov.uk/environment/nanotech/nrcg/pdf/nanoparticles-riskreport.pdf
EC Scientific Committee on Emerging and Newly-Identified Health Risks	March 2006	Opinion on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies	ec.europa.eu/health/ph_risk/committees/04_scenihp/docs/scenihp_o_003b.pdf
Woodrow Wilson International Center for Scholars	July 2006	Nanotechnology: A Research Strategy for Addressing Risk	http://www.nanotechproject.org/file_download/77

times today's spending under the NNI. This figure is not an arbitrary number, but represents a consensus widely held in industry and among non-governmental organizations formed by bottom-up calculations, analogy to other materials, and calculations that figure the costs as an "insurance premium" for nanotech development.

Towards these ends, Lux Research has joined with a broad consortium of nanotech stakeholders, including leading corporations active in nanotech (like Air Products & Chemicals, BASF, Degussa, and DuPont), non-governmental organizations (like Environmental Defense, the Natural Resources Defense Council, and the Union of Concerned Scientists), prominent nanotech start-ups (like Altair Nanotechnologies and Carbon Nanotechnologies Inc.), and business associations (like the NanoBusiness Alliance). This coalition has petitioned the Senate Committee on Appropriations both to increase funding for nanotech EHS research, and to allocate \$1 million to the National Institute of Environmental Health Sciences and the National Academy of Sciences to develop a specific game plan for the U.S. government's approach to nanotech EHS research. We encourage Committee members to support these efforts.

Better Research on Real Risks Will Help Address Perceptual and Regulatory Ones

There is less that Congress can do to aid with perceptual risks, and while regulation clearly falls into the federal government's remit, key decisions need to be made at regulatory agencies. However,

successfully addressing the basic research needs around real risks will help make significant progress on these challenges as well. Consider that:

- **Better understanding will drive regulation.** Regulatory transparency is important for nanotech's commercial development, but agencies are hesitant to issue specific guidance, even on general principles, without a better scientific understanding of the issues involved. While we still think agencies can do more to communicate their thinking to industry and to set specific regulatory expectations in a timely fashion, the basic research spurred by additional investments and research prioritization alone will help them set firm plans.
- **Lack of knowledge – and of regulations – are major drivers of perceptual risks.** One of the most significant “fright factors” identified for new technologies is “poor understanding by science or responsible agencies,” which certainly describes nanotech today.¹² Moreover, arguments that nanotech is unregulated are widely used by groups calling for restrictions on development. By addressing this lack of understanding and abetting regulatory efforts, Congress can help promote informed public understanding of nanotechnology's benefits and risks.

Addressing Nanotech EHS Risks Has a Big Economic Payoff

Nanotechnology continues to move forward rapidly in the U.S. – just in the last three months, Freescale Semiconductor has shipped pioneering nano-enabled memory chips, and Becton Dickinson has partnered to develop new nano-enabled medical diagnostics that could revolutionize disease testing. While we calculate that \$32 billion in nano-enabled products were sold in 2005 and project that \$150 billion will be in 2008, and that by the middle of the next decade this value will figure in the trillions of dollars globally. The U.S. has faced new EHS issues from previous broad technology waves, like semiconductors and polymers, in the past, and addressed them effectively; it's important that we do so for nanotechnology as well – since the challenges facing our country in achieving energy independence, finding curing for debilitating diseases, securing the homeland, and creating new jobs and economic growth all benefit from nanoscale science and engineering.

Endnotes

- 1 See the May 2005 Lux Research report "A Prudent Approach to Nanotech Environmental, Health, and Safety Risks," the November 17, 2005 Lux Research written congressional testimony "Nanotech Environmental, Health, and Safety Risks: Action Needed," and the May 2006 Lux Research report "Taking Action on Nanotech Environmental, Health, and Safety Risks".
- 2 For more information on the value of products sold incorporating emerging nanotechnology, see the February 2006 Lux Research report "How Industry Leaders Organize for Nanotech Innovation."
- 3 This testimony focuses on a specific class of nanomaterials, namely nanoparticles – purposefully engineered bits of matter size-dependent properties and sub-100 nm dimensions. They may either be miniature chunks of established materials (like Nanophase's nanoscale zinc oxide, used in sunscreens), or highly ordered structures that only form at the nanoscale (like CarboLex's single-walled carbon nanotubes, which may be soon used in flat-panel displays). We specifically do not address bulk materials with nanostructured features (like Apollo Diamond's nanostructured synthetic diamond) or nanoporous materials that have nano-sized holes (like Argonide's nanoporous ceramic water filtration media) because these materials appear unlikely on current evidence to pose novel EHS risks. We also do not address "incidental nanoparticles" which have nanoscale dimensions but have not been purposefully engineered, like the ultrafine carbon particles emitted in diesel exhaust. It's important to note that "nanotechnology does not equal nanoparticles" and that many nanotech applications, like a wide variety of next-generation semiconductor technologies, do not involve the use of any nanoparticles at all.
- 4 "[60]Fullerene is a Powerful Antioxidant in Vivo with No Acute or Subacute Toxicity." Gharbi, N.; Pressac, M.; Hadchouel, M.; Szwarc, H.; Wilson, S.R.; Moussa, F. *Nano Letters* **2005**, *5*, 2578-85, and "The Differential Cytotoxicity of Water-Soluble Fullerenes." Sayes, C.M. ; Fortner, J.D.; Guo, W.; Lyon, D.; Boyd, A.M.; Ausman, K.D.; Tao, Y.J.; Sitharaman, B.; Wilson, L.J.; Hughes, J.B.; West, J.L.; Colvin, V.L. *Nano Letters* **2004**, *4*, 1881-1887.
- 5 "The public and nanotechnology: How citizens make sense of emerging technologies." Scheufele, D.A., Lewenstein, B.V. *J. Nanoparticle Res.* **2005**, *7*, 659-667.
- 6 "Nanotech's big issue," Gewin, V., *Nature* **2006**, *443*, 137.
- 7 See the May 2005 Lux Research report "A Prudent Approach to Nanotech Environmental, Health, and Safety Risks" and the November 17, 2005 Lux Research written congressional testimony "Nanotech Environmental, Health, and Safety Risks: Action Needed."
- 8 Science Citation Index as of May 21, 2005; search terms "(toxic* OR toxico*) AND (X)", where X = (quantum dot OR nanopartic* OR nanotub* OR fulleren* OR nanomaterial* OR nanofib* OR nanotech* OR nanocryst* OR nanocomposit* OR dendrimer*) or X = (poly* OR copoly* ANDNOT polychlorinated).
- 9 The ICON database can be found at http://icon.rice.edu/centersandinst/icon/resources.cfm?doc_id=8597. The ILSI report was published as "Principles for characterizing the potential human health effects from exposure to nanomaterials: elements of a screening strategy" Oberdörster, G.; et al. *Particle and Fibre Toxicology* **2005**, *2*:8. Other review article used were: (a) "Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles." Oberdörster, G.; Oberdörster, E.; Oberdörster, J.; *Env. Health Perspect.* **2005**, *113*, 823-839. (b) "Airborne nanostructured particles and occupational health." Maynard, A.D.; Kuempel, E.D. *J. Nanoparticle Res.* **2005**, *7*, 587-614. (c) "Industrial application of nanomaterials – chances and risks." Luther, W., ed. Future Technologies Division, VDI Technologiezentrum (sponsored by the EC Nanosafe program). With over 1300 records in the ICON database, readers may be surprised that so few are used in our analysis. ICON's database includes many articles on incidentally-produced nanoparticles (such as those found in diesel exhaust or generated by welding), as well as articles on environmental or health applications of nanomaterials, such as the use of iron nanoparticles in wastewater remediation or polymer nanoparticles in drug delivery. Such studies can contain helpful information on hazard or exposure, but are of less direct use for trying to understand the risks of their own materials than those that squarely address EHS questions.
- 10 Oberdörster, G.; Ferin, J.; Lehnert, B.E. *Environ. Health Perspect.* **1994**, *102*, Supplement 5, 173-179; "Pulmonary Instillation

Studies with Nanoscale TiO₂ Rods and Dots in Rats: Toxicity Is Not Dependent upon Particle Size and Surface Area.” Warheit, D.B.; Webb, T.R.; Sayes, C.M.; Colvin, V.L.; Reed, K.L. *Toxicol. Sci.* **2006**, *91*, 227-236; Warheit, D.B., personal communication.

- 11 A key exception to this rule lies with start-up companies. As we have previously stated to the House Committee on Science, start-ups are both generally the earliest commercial developers of new nanoparticles and also the parties least likely to be able to afford expensive toxicology studies. As long as these dynamics hold, there will be a market failure that only government can correct. We continue to believe that a market-based mechanism, which would require companies receiving government funding for products that incorporate nanoparticles to submit their materials for anonymous testing as a condition of the grant, is the most efficient way to ensure that scarce government research funds are allocated efficiently to materials of greatest commercial interest. Such a mechanism would place a new requirement on small businesses receiving Small Business Innovation Research and/or Small Business Technology Transfer grants, but because the only requirement is the submission of a small amount of material for anonymous testing with no financial or onerous documentation requirements, it does not seem to our layman’s eyes to represent an undue burden.
- 12 Bennett, P.; Calman, K. *Risk Communication and Public Health*. Oxford University Press, Oxford, 1999.